# CLASSIC Proactive Telephone Coaching and Tailored Support (PROTECTS)

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
19/06/2014		Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
19/06/2014		[X] Results		
Last Edited	Condition category	Individual participant data		
31/05/2018	Other			

#### Plain English summary of protocol

Background and study aims

The Salford Integrated Care Programme (SICP) is a large scale project to improve care for older people with long-term conditions and social care needs in Salford. The aim of this study is to test the effectiveness of telephone health coaching for older patients (aged 65+) with multiple long-term conditions (multi-morbidity), compared to usual care.

#### Who can participate?

Patients aged 65+ with two or more existing long-term conditions and assessed as needing some assistance with self-management.

#### What does the study involve?

Patients receive a 20-minute phone call once a month for 6 months which is delivered by experienced health advisers. The health advisers and the patient agree a plan for management of their long-term conditions, including advice on healthier diet, exercise, reduction of smoking and alcohol consumption and increased social activity, as well as support for low mood (if applicable).

What are the possible benefits and risks of participating?

Previous evidence suggests that health coaching may be effective in improving outcomes, including self-management and quality of life. However, these benefits have not been confirmed for older patients with multi-morbidity in the UK NHS. The trialists are not aware of any adverse effects from health coaching

Where is the study run from? University of Manchester (UK)

When is the study starting and how long is it expected to run for? July 2014 to September 2016

Who is funding the study? NIHR Health Services and Delivery Research (UK) Who is the main contact?
Prof. Peter Bower
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### **Contact information**

#### Type(s)

Scientific

#### Contact name

Prof Peter Bower

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#### Additional identifiers

Protocol serial number

16717

## Study information

#### Scientific Title

CLASSIC Proactive Telephone Coaching and Tailored Support (PROTECTS): a pragmatic, two-arm, patient-level, randomised trial of the effectiveness of telephone coaching and support for older people with multimorbidity

#### **Acronym**

CLASSIC Proactive Telephone Coaching and Tailored Support (PROTECTS)

#### **Study objectives**

The Salford Integrated Care Programme (SICP) is a large scale transformational project to improve care for older people with long-term conditions and social care needs in Salford. SICP will deliver improved care through 3 core mechanisms:

- 1. Improved access to community resources and targeted support for self-management
- 2. Better integration of care through multidisciplinary health and social care groups providing structured, population based care.
- 3. An 'Integrated contact centre' to support navigation and self-management

The Comprehensive Longitudinal Assessment of Salford Integrated Care (CLASSIC) is an evaluation framework designed to provide a rigorous test of the ability of the SICP to deliver enhanced experience of care, improved well-being and quality of life, and reduced costs of care and improved cost effectiveness. The CLASSIC evaluation framework will adopt the cohort

multiple randomised controlled trial, where a large population cohort is recruited and followed over time, with subgroups of the cohort used to evaluate the outcomes of particular SICP components.

An important component of the SICP is a contact centre providing 'health coaching'. Health coaching involves 'a regular series of phone calls between patient and health professional...to provide support and encouragement to the patient, and promote healthy behaviours such as treatment control, healthy diet, physical activity and mobility, rehabilitation, and good mental health'.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

- 1. First MREC approval date 29/04/2014, ref: 14/NW/0206
- 2. Health Coaching Sub Project (Leeds East), approval date 26/05/2015, ref: 15/YH/0129

#### Study design

Both; Interventional and Observational; Design type: Process of Care, Treatment, Cohort study

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Topic: Primary Care, Ageing; Subtopic: Not Assigned, Ageing; Disease: All Diseases, All Ageing

#### **Interventions**

Current interventions as of 10/03/2016:

The CLASSIC framework includes a large cohort of patients, which we will sample to recruit patients for a trial using the cohort multiple randomised controlled trial methodology (Relton et al 2010). The trial is called CLASSIC PROTECTS (Proactive Telephone Coaching and Tailored Support), which tests the effectiveness of telephone health coaching on the outcomes of older patients (aged 65+) with multiple long-term conditions, compared to usual care. 1306 eligible patients in the CLASSIC cohort will be randomly selected and 504 asked if they would take part in a trial of health coaching for multiple long-term conditions – a 20-minute phone call each month for 6 months. The remaining 802 will act as controls for the study, and will be followed up as part of the CLASSIC cohort.

#### Previous interventions:

The CLASSIC framework includes a large cohort of patients, which we will sample to recruit patients for a trial using the cohort multiple randomised controlled trial methodology (Relton et al 2010). The trial is called CLASSIC PROTECTS (Proactive Telephone Coaching and Tailored Support), which tests the effectiveness of telephone health coaching on the outcomes of older patients (aged 65+) with multiple long-term conditions, compared to usual care. 504 eligible patients in the CLASSIC cohort will be randomly selected and 50% (n=252) asked if they would take part in a trial of health coaching for multiple long-term conditions – a 20-minute phone call each month for 6 months. The remaining 50% will act as controls for the study, and will be followed up as part of the CLASSIC cohort.

#### Intervention Type

Behavioural

#### Primary outcome(s)

Current primary outcome measures as of 13/12/2016:

- 1. Ability to self-manage, measured using the 13-item version of the Patient Activation Measure
- 2. Quality of life, measured using the physical health domain of the World Health Organization Quality of Life (WHOQOL-BREF) instrument

Timepoint(s): Month 0, 20

Previous primary outcome measures from 10/03/2016 to 13/12/2016:

Health outcomes; Timepoint(s): Month 0, 6

Original primary outcome measures:

Health outcomes; Timepoint(s): Month 0, 6, 12, 18, 24

#### Key secondary outcome(s))

Current secondary outcome measures as of 13/12/2016:

- 1. Depression, assessed using the Mental Health Inventory-5
- 2. Ability to self-manage, assessed using the Summary of Diabetes Self-Care Activities (SDSCA) measure
- 3. Health economic analyses using the EQ5D-L measure and healthcare utilisation data Timepoint(s): Month 0, 20

Previous secondary outcome measures from 10/03/2016 to 13/12/2016:

- 1. Costs; Timepoint(s): Month 0, 6
- 2. Patient experience; Timepoint(s): Month 0, 6

Original secondary outcome measures:

- 1. Costs; Timepoint(s): Month 0, 6, 12, 18, 24
- 2. Patient experience; Timepoint(s): Month 0, 6, 12, 18, 24

#### Completion date

30/09/2016

# Eligibility

#### Key inclusion criteria

- 1. Aged 65+
- 2. 2 or more existing long-term conditions
- 3. Assessed as needing some assistance with self-management (defined in terms of scores on the Patient Activation Measure)

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

#### Senior

#### Sex

All

#### Key exclusion criteria

- 1. Patients in the palliative care stage of condition
- 2. Those with conditions which reduce capacity to consent and participate

#### Date of first enrolment

01/07/2015

#### Date of final enrolment

01/07/2016

#### Locations

#### Countries of recruitment

**United Kingdom** 

England

# Study participating centre University of Manchester

5th Floor, Williamson Building Manchester United Kingdom M13 9PL

# Sponsor information

#### Organisation

University of Manchester (UK)

#### **ROR**

https://ror.org/027m9bs27

# Funder(s)

#### Funder type

Government

#### Funder Name

Health Services and Delivery Research Programme (Grant Codes: 12/130/33)

#### Alternative Name(s)

Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

#### **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/07/2017		Yes	No
Results article	trial within a cohort results	30/05/2018		Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes